



Collaboration

Evaluation of the provision of food risk assessment services by the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) during 2013-2017

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Abstract

Between 2013 and 2017, the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AE-COSAN) has provided risk assessment services at the request of external applicants and in the framework of the authorisation procedures for novel foods and for the assessment of the safe use of processing aids.

On completion of these risk assessments, external applicants were sent a questionnaire about their opinion of the service provided.

During this period, 26 applicants were surveyed: 20 from Spain, 5 from Latin America and 1 from the United States. Answers were received from 25 of these. The applications were in regard to substantial equivalences to already authorised novel foods (19), novel foods for new authorisation (4) and processing aids (3).

The main difficulty encountered by applicants was finding laboratories to conduct the required determinations. The most positive aspect were the clear instructions and the personal attention and support received, which obtained the maximum score from all the survey participants.

From the answers received, the overall opinion of the assessment service provided from 2013 to 2017 is extremely positive.

Key words

AECOSAN, risk assessment, provision of services, satisfaction.

1. Introduction

In accordance with Law 11/2001, of 5 July, establishing the Spanish Food Safety Agency, one of the functions of the Spanish Agency for Consumer Affairs, Food Safety and Nutrition is to act as a national reference centre for food risk assessment (BOE, 2001). Meanwhile, Royal Decree 19/2014, of 17 January, which merges the independent bodies of the National Consumer Institute and the Spanish Agency for Food Safety and Nutrition into a new independent body called the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) and approves its statute, assigns AECOSAN the function of providing the relevant authorities with technical support and risk assessments in food safety matters for use in their regulatory and executive procedures, while facilitating the coordination of the entities involved (BOE, 2014).

In this regard, AECOSAN has been providing risk assessment services for novel foods using the general and substantial equivalence procedures described in Regulation (EC) No 258/97 concerning novel foods and novel food ingredients (EU, 1997a) and risk assessment of the use of processing aids.

The assessments of the dossiers of these products have been carried out at the request of external applicants and are subject to public fees or prices. The fee is applied when the service is not voluntarily requested or is not provided or performed by the private sector, and the public price when, such services also being provided by the private sector, they are voluntarily requested by those supplied. There are currently several standards that require an assessment by the Scientific Committee of AECOSAN prior to the authorization of the use of certain products and, therefore, these assessments would be subject to the charging of fees. These standards concern the use of processing aids for the production of certain sugars intended for human consumption (BOE, 2003), basic materials for the manufacture of chewing gum (BOE, 2010), polymeric materials that are to come into contact with foodstuffs (BOE, 2011a) and the manufacture of edible vegetable oils (BOE, 2015).

Among the fees for services provided by AECOSAN, one of the taxable items is the carrying out of assessments of foodstuffs, food ingredients, processing aids or technological processes (BOE, 2011b). In the case of public prices, these are established for activities such as the assessment of dossiers relating to processing aids, technological processes, foodstuffs and food ingredients or scientific advice on food risk assessment (BOE, 2009).

Knowledge of the degree of satisfaction of citizens with the public services provided is important for allocating resources and making decisions in the management of these services. In Spain, both at national (MINHFP, 2018), regional (Catalonia, 2016) and local (Madrid, 2017) levels, and in most countries belonging to the Organisation for Economic Cooperation and Development (OECD), the degree of satisfaction of citizens with public services is verified, although differences in survey methodologies limit the comparison of results (OECD, 2017).

At the national level, the improvement of the quality of the services provided is fostered through a general framework that aims to improve quality in the General State Administration and which is made up of a set of programmes to improve the quality of public services, provide the public authorities with consolidated information for decision-making in this regard and promote transparency

by providing the general public with information on the level of quality offered to citizens. One of the instruments considered in this framework consists of demand analysis studies and surveys to assess user satisfaction with the public services provided. The purpose of this user satisfaction assessment study is to measure users' perception of an organisation and the services it provides (BOE, 2005).

In our case, it was considered important to know the degree of satisfaction of external applicants for risk assessment services. Given the scientific and technical nature of this service, the applicant does not always have the necessary knowledge to judge the quality of the assessments carried out but, in any event, they are able to judge other aspects of the service provided.

Although the provision of these risk assessment services in AECOSAN is not currently subject to quality certification, the criteria of standards such as the UNE-EN ISO 9000:2015 (ISO, 2015a) standard has been followed, which establishes that one of the possible measures in relation to customer focus, which is one of its quality management principles, is to measure and monitor customer satisfaction and take appropriate action. In this regard, the UNE-EN ISO 9001:2015 (ISO, 2015b) standard on quality management systems concerns the satisfaction of the customer to whom products or services are provided and states that the organisation must monitor the perception of customers on the degree to which their needs and expectations are met. To this end, the standard specifies a number of examples of monitoring, including customer surveys.

Other quality standards also refer to the collection of information regarding the services provided. Thus, the UNE-EN ISO/IEC 17025:2017 standard on general requirements for the competence of testing and calibration laboratories (ISO, 2017) states that the laboratory should seek feedback, both positive and negative, from its customers and that this feedback, including customer satisfaction surveys, should be reviewed and used to improve the management system, laboratory activities and customer service.

Following the criteria of this type of standard, and taking into account that the service provided is a one-off event, referred to a specific assessment service that may be subject to a direct measurement of the applicant's satisfaction regarding the fulfilment of its requirements by AECOSAN, upon completion of the risk assessment of dossiers for novel foods and processing aids, the Risk Assessment Area of the Subdirectorate-General for Food Safety Promotion of AECOSAN has been conducting a survey on external risk assessment applicants to find out their opinion on the quality of the service provided.

Knowing the opinion of these applicants is necessary to improve both the working procedures and their satisfaction with the public service provided.

The purpose of this work has been to assess the opinions received from external risk assessment applicants on the services provided over the past 5 years. For the purposes of this publication, assessments of novel foods requested under the substantial equivalence procedure shall be referred to as substantial equivalences to distinguish them from applications for the assessment of novel foods which followed the general procedure and that shall be referred to as novel foods.

2. Survey

A survey was designed in order to measure the satisfaction of applicants with the risk assessment services provided by AECOSAN directly. It should be noted that, in most cases, the contact of the applicants with AECOSAN is an isolated event, referring only to the assessment service provided through the issue of a report, so it is not possible to obtain their opinion on other services or to assess the changes in their level of satisfaction over time.

The survey used consists of 20 questions and is divided into four sections to find out the opinion of the applicant before contacting AECOSAN, when contacting AECOSAN and during and after the provision of the service by AECOSAN (Table 1). Most of the questions give five answer options (e.g. very high, high, medium, low or very low price) and also the possibility of marking "I don't know". In addition, there are free answer questions where comments on the most positive and negative aspects to be highlighted can be included.

The survey was sent in a word processor file and could be answered by checking the chosen answer with a mark or colour on the file or by hand and scanning the form to send it by email.

Table 1. Questions from the AECOSAN risk assessment service provision survey

Before contacting

- A- Did you have any difficulty in finding out which body was responsible for providing the service you were interested in? (yes, some/yes, a lot/no, none)
- B- Were you aware of the existence of AECOSAN before you knew which body you should go to? (yes/no)

When contacting

- C- Was it easy to find the information on the AECOSAN website about the procedure or service you were interested in? (from very difficult to very easy)
- D- Was the information you found on the website useful? (from useless to very useful)
- E- Did you find it easy to contact the AECOSAN personnel responsible for the procedure you were interested in?

During the provision of the service

- F- The duration of the whole process seemed: (from very long to very short)
- G- The time you needed to prepare the dossier seemed: (from very long to very short)
- H- What difficulties did you have in preparing the dossier?
- I- The time it took AECOSAN to provide the service seemed: (from very long to very short)
- J- The cost of the provision of the service (tax or public price) seemed: (from very high to very low)
- K- The instructions you received from AECOSAN were: (from very unclear to very clear)
- L- The support you received from AECOSAN to prepare your dossier was: (from very little to very much)
- M- The personal assistance you received from AECOSAN during the process was: (from very poor to very good)
- N- The report you received seemed: (from poor to very good)
- 0- Did you receive assistance from other external entities to prepare the dossier (e.g. consulting firms)?
- P- In the event of having used external assistance, you consider that this assistance was: (from useless to very necessary)

Table 1. Questions from the AECOSAN risk assessment service provision survey

After the provision of the service

- Q- Overall opinion regarding the service provided by AECOSAN: (from very bad to very good)
- R- Opinion on the service provided compared to other similar services of which you are aware (from much worse to much better)
- S- The most positive thing to mention is:
- T- The most negative thing to mention is:

3. Applicants surveyed

In 2015, 10 applicants whose assessments had been conducted in 2013 (2), 2014 (1) and 2015 (7) were asked to complete the survey. The applications for evaluation concerned novel foods (1), substantial equivalences (8) and processing aids (1). The applicants were from Spain (8), Mexico (1) and Argentina (1).

In 2016, 8 applicants whose assessments had been conducted in the same year were asked to complete the survey. The applications for assessment concerned substantial equivalences (7) and processing aids (1). The applicants were from Spain (5), Argentina (1), Ecuador (1) and Paraguay (1).

Finally, in 2017, 8 applicants for the assessment of novel foods (3), substantial equivalences (4) and processing aids (1) were asked to complete the survey. Of the 8 applicants, 7 were from Spain and 1 from the United States.

Thus, in the period 2013-2017, 26 applicants were surveyed (20 Spanish (77 %), 5 Latin American (Argentina (2), Ecuador, Mexico and Paraguay) and 1 from the United States); responses were obtained from 25 of them. Their applications were for substantial equivalences (19), novel foods (4) and processing aids (3) (Figure 1).

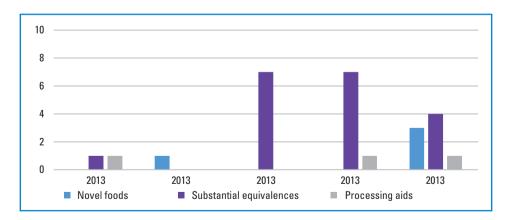


Figure 1. External applications to AECOSAN for risk assessments 2013-2017

4. Opinions of external applicants for risk assessments in the period 2013-2017

4.1 Opinion before contacting AECOSAN

60 % of the applicants who completed the survey had no difficulty in finding out which body was responsible for providing the service in which they were interested, while 40 % did have some difficulty. 72 % were aware of the existence of AECOSAN before submitting their application and only 28 % were unaware of it. Of the latter, the vast majority (71 % of those who were unaware of its existence) were foreign applicants.

4.2 Opinion when contacting AECOSAN

67 % of the applicants who completed the survey found information on the AECOSAN website about the procedure or service they were interested in easily or very easily and 60 % found the information they found on the website useful or very useful; only 16 % found the information on the website useless or not very useful (Figure 2).

72 % found it easy to contact the people in AECOSAN responsible for the procedure they were interested in.

4.3 Opinion during the provision of the service by AECOSAN

The whole process, from the time the applicant decided to prepare the dossier to the time the service was provided, seemed short or very short to 54 % of the applicants and of intermediate duration to 25 %. Within this time, 2 periods can be distinguished:

- The time taken by the applicant him/herself to prepare the documentation before formally submitting it to AECOSAN seemed long or very long to 36 % of the applicants and of intermediate duration to 52 %.
- In contrast, the time taken by AECOSAN to provide the service seemed short or very short to 72
 % of the applicants and only 2 applicants (8 %) considered it to be long or very long.

What applicants found least difficult was knowing what they had to submit, and what they found most difficult was finding laboratories to do the analyses they were required to do. In this regard, the instructions they received from AECOSAN were considered very clear by 76 % of the applicants and clear to 24 % (Figure 3). Five applicants used the services of a consultant, three of whom felt that such external assistance was necessary.

100 % of the applicants felt that the support they received from AECOSAN to prepare their dossier was a lot or very much (Figure 4) and that the personal assistance they received from AECOSAN during the process was very good (Figure 5).

The fee or public price for the provision of the assessment service seemed high to 24 % of the applicants and medium to 56 % (Figure 6).

The assessment report received was considered very good by 68 % of the applicants and good by the remaining 32 % (Figure 7).

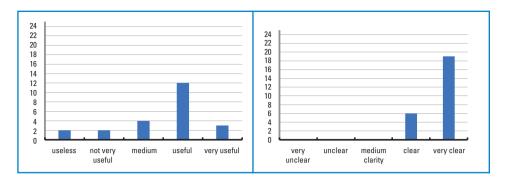


Figure 2. Usefulness of the information on the website Figure 3. Instructions received from AECOSAN

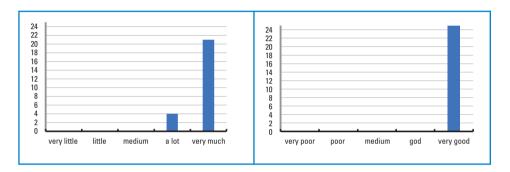


Figure 4. Support received from AECOSAN

Figure 5. Personal assistance received from AECOSAN

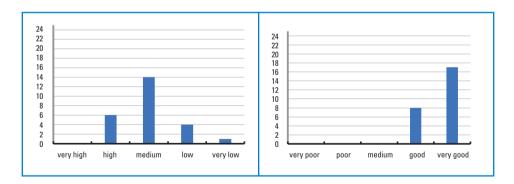
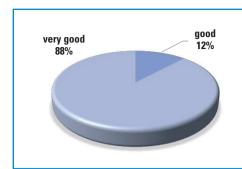


Figure 6. Cost of service provided by AECOSAN

Figure 7. Report issued by AECOSAN

4.4 Opinion after the provision of the service by AECOSAN

The overall opinion regarding the service provided by AECOSAN was very good (88 %) or good (12 %) (Figure 8). Compared to other similar services of which they were aware, the applicants indicated that the service provided by AECOSAN was much better (52 %) or better (43 %) (Figure 9).



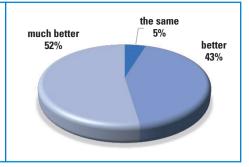


Figure 8. Overall opinion on the service provided by AFCOSAN

Figure 9. Comparison of the service provided by AE-COSAN with other similar services known to the applicant

4.4.1 Comments received

In the survey, respondents were given the opportunity to comment on the most positive and negative aspects of the service. 23 of the 25 applicants who completed the survey commented on the most positive and 8 on the most negative aspects. The most positive aspect highlighted by the respondents was the assistance and information provided (Table 2).

Table 2. Positive comments received on the risk assessment services

- The assistance and information provided by AECOSAN staff.
- The assistance provided by the staff who helped us arrange the service. They were concerned, helpful and very professional from beginning to end.
- I always received complete, correct and timely information in a friendly and detailed manner. Thank you
 very much for your excellent service and promptness. I get the impression that in AECOSAN the person
 who handles our case is the same throughout the process until the conclusion of the assessment. There
 is no downtime, everything is very streamlined. They give detailed and precise instructions, which is important to complete the process in a reasonable time. We had to wait for results from the laboratories but
 this was a cause external to AECOSAN.
- The professionalism, reliability and collaboration of AECOSAN.
- · Personalized assistance and support throughout the process.
- The personal assistance received.
- · Personalized assistance.
- Availability and support of the necessary technical staff.
- The work they have done is invaluable, in a totally personalized way, much faster and more effective than only through official queries to and responses from a public body, when most of the time the great doubt is whether there is someone at the other end, whether they have received my communication, whether they have fully understood what we wanted to convey or only half understood it.... The anxiety caused by the situation I am describing has been completely absent in your case.
- · The team's commitment when providing the service.

Table 2. Positive comments received on the risk assessment services

- Remarkable professionalism. Excellent and friendly personal assistance and unflagging predisposition.
 Precise, clear and quick response.
- ... I would like to take this opportunity to highlight the assistance received from the staff, who were always
 perfectly cooperative and helpful with every query. Without them, we would not have achieved our objective. We would like to express our deepest gratitude, explicitly and publicly.
- Excellent advice.
- The assistance, service and support received from AECOSAN staff and the Scientific Committee.
- Speed, interest and support in every step of the process.
- The assistance received.
- The quality of the personal attention, the willingness to help, and the speed and technical professionalism in the handling of the process.
- The assistance of the person responsible for processing the application.
- Simple explanations by the assessor. Precise guidance. Help at all times in an operational and very fast way.
 The assessor and the technical consultant work together in a very organized way.
- The great knowledge acquired and the collaboration of the AECOSAN technical staff without whom the
 preparation of the dossier would not have been possible.
- Speed and precision in answering any doubts or questions raised.
- The attention and facilities provided by the staff throughout the process.
- The clarity of the instructions and the speed with which the procedure was completed once we had compiled the requested documentation. We were very satisfied with the AECOSAN service. They made the handling of the process much easier for us.

As for the comments received on the most negative aspects, only 8 of the applicants made comments. Of these, 4 concerned laboratory issues (cost, time, availability or quality requirements), 2 concerned the duration of the process, 1 the cost of the fee and 1 the initial contact with AECOSAN. Of these, 7 were applicants for substantial equivalence assessments and 1 for a processing aid assessment (Table 3).

Table 3. Negative comments received from applicants for risk assessment services

- Laboratory analyses to prepare the dossier very costly.
- Time taken: very long.
- Requirements on laboratory conditions, given the almost non-existence of compliance as required by the standard, even in the European territory itself.
- Difficulty in obtaining national laboratories.
- · Cost of the fee.
- The long time the whole process took.
- · Waiting for labs and tests.
- Completing the contact form available on the AECOSAN website did take a long time (12 days). This contact system could almost certainly be speeded up by providing an email address for queries on the website.

Discussion

The survey was conducted among applicants who completed the submission of a dossier. It should be noted that of the 114 external entities interested in submitting a dossier for assessment and to which information and instructions were provided in the last three years, only 20 % finally submitted it.

The survey was answered by 25 of the 26 applicants surveyed, the vast majority of whom responded within 3 days of receiving the survey and many of whom responded on the same day it was sent to them. The high response rate and the speed with which the survey was completed demonstrate that it is sufficiently clear and simple to complete. There are systems for completing online surveys that could simplify their completion and processing but given the small number of respondents each year and the high response rate, the system used was perfectly adequate for estimating the quality of the service provided.

Most of the applicant companies were Spanish, although 3 of them had links with Latin America. Although some applicants had difficulty in finding out that AECOSAN was the competent body for providing the service they needed, it was easy for them to contact the staff responsible once they did find out and their rating of the usefulness of the information available on the website was positive.

The service delivery times did not seem long to them, but they did find the time they needed to prepare the documentation excessive. However, some applicants tend to minimise the time it took them to prepare their application and to maximise the time it took the Agency to issue its report, by mixing the 2 periods.

For example, in 2015, one of the applicants for substantial equivalence took a total of 181 days from his/her first query to the submission of the application and AECOSAN took a total of 22 days to respond to 3 queries, review 4 draft dossiers and prepare the assessment report. Although the applicant took 90 % of the time, his perception of the time taken to provide the service is biased. Thus, although only 7 days elapsed between the formal submission of the final application for assessment and the submission of the report by AECOSAN (the average for assessing substantial equivalence of novel foods in 2015 was 9 days from the day the application was submitted to the AECOSAN registry), the applicant responded in the survey that the time taken by the Agency to provide the service was of intermediate duration.

In the same vein, in June 2016 one applicant asked about the formalities necessary to apply for the assessment of substantial equivalence and he/she was sent all the necessary information on the same day. The application with all the required documentation and payment of the fee was submitted to the AECOSAN Registry 5 months later and the AECOSAN report was issued 5 days after that. When completing the survey, the applicant indicated that the time taken by AECOSAN to provide the service was very long when the time taken by the Agency was only 5 days and the rest of the time was taken by the applicant to prepare the dossier.

In any event, the degree of general satisfaction with the time taken by AECOSAN to provide the risk assessment service is high, as is satisfaction with the final report issued. The level of satisfaction of the applicants in relation to the support they received from the Agency to prepare their

dossier and the personal attention they received during the process is also very high. It should be noted that applications involve the submission of a dossier containing a wide range of scientific and technical information. Although there were some guidelines for novel foods (EU, 1997b), substantial equivalences (EU, 2013) (ACNFP, 2005) or processing aids (AECOSAN, 2010), the information to be presented depends largely on the characteristics of each specific product.

Although, in general, if you have your own staff with a technical profile, you would not need to use consultancy services to prepare many of these dossiers, 3 of the 5 applicants who did use consultancy services seem satisfied.

The main difficulty for applicants was finding laboratories to carry out the required analyses. The quality of the analytical results provided had to be guaranteed by the accreditation of the laboratories to carry out the measurement of each parameter in accordance with the UNE-EN ISO/IEC 17025:2005 standard (ISO, 2005). In this regard, for some measurements, it was difficult to find accredited laboratories due to the unusual nature of the parameter or because the scope of accreditation did not cover the product or food subject to the application for assessment. In these cases, in view of the difficulty in providing results supported by certification, data on the validation of the method used were requested.

The fee was considered high by one third of the applicants for substantial equivalence although it has increased very little over this period, from EUR 1 010 in 2013 to EUR 1 040.60 in 2018. On the other hand, the cost was considered intermediate by applicants for more complex procedures such as novel foods or processing aids.

The most positive aspect for the applicants was the clarity of the instructions and the personal support and assistance they received, which they all gave the highest rating.

According to the responses received, the overall opinion of the assessment service provided in the period 2013-2017 is very positive. This opinion is related to the support provided to the applicant during the process, which is necessary given the diversity of cases presented and the complexity of the information to be provided. This support also helps applicants to get to know the dossier in depth before its formal submission, so the time required to issue the reports is much shorter and the chances of a positive assessment are greater if the assessors' recommendations have been followed.

As for the possibilities for improvement, the most negative aspect is the cost of some procedures, followed by information on the website. The latter, although it did not receive a poor rating, could be improved more easily than the cost.

These surveys have been carried out among external applicants who have completed the submission of a dossier. The procedure for the assessment of novel foods has changed since the entry into force of Regulation (EU) 2283/2015 (EU, 2015) in 2018 and, in accordance with this Regulation, the initial assessments of novel foods are no longer conducted by the Member States of the European Union and the measurement of the substantial equivalence of novel foods has disappeared, and it is therefore expected that the number of external applicants for risk assessments will decrease. However, the service is also provided to internal applicants for risk assessment reports from the Scientific Committee, who may also be subject to satisfaction surveys regarding the service provided.

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